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**PATENT**

Attorney Docket No. A-68983-2

Dorsey File No. 469443-00065

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

*In re* application of:

HORWITZ

Serial No.: 10/772,768

Filing Date: February 4, 2004

For: *Method to Prevent Graft Rejection  
Using TGF-Beta to Induce T  
Suppressor Cells*

Examiner: To Be Assigned

Art Unit: 1644

CERTIFICATE OF MAILING

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Date:

*January 25, 2005*  
*Careyna P. Fujimoto*  
Signed: Careyna P. Fujimoto

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450  
Sir:

In satisfaction of the duty of disclosure under 37 C.F.R. § 1.56, and in accordance with the provisions of 37 C.F.R. §§ 1.97 and 1.98, Applicants wish to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/08A-B. This application is a continuation of U.S. Application Serial No. 09/833,526, filed on April 11, 2001 (now U.S. Patent No. 6,759,035). Applicant wishes to draw the attention of the U.S. Patent and Trademark Office to the references cited on the accompanying form PTO/SB/08A-B, Substitute for form PTO-1449, marked without an asterisk (\*). Since these references were

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Filing Date: February 4, 2004

previously disclosed in the above-mentioned application, in accordance with 37 C.F.R. § 1.98(d), no copies of these references are enclosed.

Further, in accordance with 1287 Off. Gaz. Pat. Office 163, October 19, 2004, no copies of U.S. patents and U.S. published applications are enclosed. All other references are enclosed.

Nothing herein shall constitute an admission concerning the contents of any of the cited references, nor shall the inclusion of a reference herein be considered an admission that the reference constitutes prior art against the invention claimed in the above-identified application. Submission of the present document shall not be construed as an admission that a search has been made or that better art does not exist.

As far as is known to the undersigned, this Information Disclosure Statement is being filed within three months of the filing date of a national application, within three months of the date of entry of the national state in an international application, or before the mailing date of a first Office Action on the merits as set forth in 37 C.F.R. § 1.97(b), and therefore no fee is required.

While no further fee is believed to be due, if this belief is in error, the Commissioner is authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-2319 (File No. 469443-00065; Docket No. A-68983-2).

USSN: 10/772,768  
Filing Date: February 4, 2004

Please direct any calls in connection with this application to the undersigned at  
(415) 781-1989.

Respectfully submitted,  
DORSEY & WHITNEY LLP

Dated: 1/25/05  
Dorsey & Whitney LLP  
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Attachments:

Form PTO/SB/08A-B, Substitute for Form PTO-1449  
3 references



Substitute for form 1449A/PTO  
(Modified)

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

## Complete if Known

Application Number	10/772,768
Filing Date	February 4, 2004
First Named Inventor	David A. HORWITZ
Art Unit	1644
Examiner Name	Not Yet Assigned
Attorney Docket Number	A-68983-2

Sheet 1 of 9

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	US 6,228,359 B1	05-08-2001	Horwitz	
	A2	US 6,358,506 B1	03-19-2002	Horwitz	
	A3	US 6,406,696 B1	06-18-2002	Bluestone	
	A4	US 6,447,765 B1	09-10-2002	Horwitz	
	A5 *	US 6,797,267 B2	09-28-2004	Horwitz	
	A6 *	US 6,803,036 B1	10-12-2004	Horwitz	
	A7 *	US 6,759,035 B2	07-06-2004	Horwitz	
	A8 *	US 2003/0012791 A1	01-16-2003	Horwitz	
	A9 *	US 2003/0039650 A1	02-27-2003	Gruenberg	
	A10 *	US 2003/0157057 A1	08-21-2003	Horwitz	
	A11 *	US 2004/0071667 A1	04-15-2004	Horwitz	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document Country Code <sup>2</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	B1	WO 93/17698 A1	09-16-1993	Schering Corporation		
	B2	WO 97/42324 A1	11-13-1997	Schering Corporation		
	B3	WO 99/25366 A1	05-27-1999	University of Southern California		
	B4	WO 99/48524 A1	09-30-1999	University of Southern California		
	B5 *	WO 00/00587 A1	01-06-2000	Kaltoft et al.		
	B6	WO 00/66158 A2	11-09-2000	University of Southern California		
	B7	WO 01/16296 A2	03-08-2001	University of Southern California		
	B8 *	WO 01/77299 A2, A3	10-18-2001	University of Southern California		
	B9 *	WO 2003/059264 A3	07-24-2003	University of Southern California		

## NON PATENT LITERATURE DOCUMENTS

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	C1	ANASETTI et al., "Treatment of acute graft-versus-host disease with a nonmitogenic anti-CD3 monoclonal antibody", Transplantation 54:844-851 (1992).	

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			Application Number	10/772,768	
			Filing Date	February 4, 2004	
			First Named Inventor	David A. HORWITZ	
			Art Unit	1644	
			Examiner Name	Not Yet Assigned	
Sheet	2	of	9	Attorney Docket Number	A-68983-2

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	C2	ASAI O, et al., "Suppression of graft-versus-host disease and amplification of graft-versus-tumor effects by activated natural killer cells after allogeneic bone marrow transplantation," <i>Journal of Clinical Investigation</i> 101(9):1835-1842 (1998).		
	C3	ASANO M, et al., "Autoimmune disease as a consequence of developmental abnormality of a T cell subpopulation." <i>J Exp Med.</i> , 184(2):387-96 (1996 Aug 1).		
	C4	AUCHINCLOSS, Hugh Jr., et al, in <i>Fundamental Immunology</i> 4th Ed., Paul, W.E. (ed.) Lippincot-Raven: Philadelphia, New York; 1999 pp. 1182-1222.		
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	C11	BONIG et al., "Transforming Growth Factor- $\beta$ Suppresses Interleukin-15-Mediated Interferon- $\gamma$ Production in Human T Lymphocytes," <i>Scand. J Immunol</i> , 50:612-618 (December 1999).		
	C12	BONINI et al., "HSY-TK gene transfer into donor lymphocytes for control of allogeneic graft-versus-leukemia, <i>Science</i> 276:1719-1724 (1997).		
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Sheet	3	of	9	Attorney Docket Number	A-68983-2

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	C19	CHEN et al., "T Cells Specific for a Polymorphic Segment of CD45 Induce Graft-Versus-Host Disease with Predominant Pulmonary Vasculitis," J. Immunology, 161:909-918 (1998).	
	C20	CHONG P. et al. "Inhibition of protein-kinase C in peripheral blood mononuclear cells of patients with systemic lupus erythematosus: effect on spontaneous immunoglobulin production," Autoimmunity, 10:227-231 (1991).	
	C21	COSIMI, A.B., et al., "Treatment of acute renal allograft rejection with OKT3 monoclonal antibody," Transplantation, 32(6):535-9 (1981 Dec).	
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	C26	DUPONT, B., "Immunology of hematopoietic stem cell transplantation: a brief review of its history," Immunol Reviews 157:5-12 (1997).	
	C27	EARLY et al., "Rapid conversion of naïve to effector T cell function counteracts diminished primary human newborn T cell responses," Clin Exp Immunol, 116:527-533, abstract (June 1999).	
	C28	FAST, "Generation and characterization of IL-2-activated veto cells", J Immunol 149:1510-1515 (1992).	
	C29	FERNANDES, G., et al., "Calorie restriction delays autoimmune murine lupus by differentially modulating oncogenes and TGF- beta-1 expression", 9th International Congress on Immunology., 848 (1995).	
	C30	FOWLER et al., "Donor CD4-enriched cells of Th2 cytokine phenotype regulate graft-versus-host disease without impairing allogeneic engraftment in sublethally irradiated mice", Blood 84:3540-3549 (1994).	
	C31	GAO Q, et al., "CD4+CD25+ cells regulate CD8 cell anergy in neonatal tolerant mice." Transplantation, 68(12):1891-7 (1999 Dec 27).	
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	C33	GOLDMAN et al., "Bone marrow transplantation for chronic myelogenous leukemia in chronic phase. Increased risk for relapse associated with T-cell depletion", Ann Intern Med 108:806-814 (1988).	
	C34	GRATAMA et al., "Treatment of Acute Graft-Versus-Host Disease With Monoclonal Antibody OKT3. Clinical results and effect on circulating T lymphocytes", Transplantation 38(5):469-474 (1984).	
	C35	GRAY et al., "Activated Natural Killer Cells Can Induce Resting B Cells to Produce Immunoglobulin," Arthritis & Rheumatism, 37(9)suppl:S378 (1994).	
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	C37	GRAY et al., "The Role of Transforming Growth Factor β in the Generation of Suppression: an Interaction Between CD8+ T and NK Cells," J Exp Med 180:1937-1942 (1994).	

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Sheet	4	of	9	Attorney Docket Number	A-68983-2

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	C38	GRIBBEN et al., "Complete blockade of B7 family-mediated costimulation is necessary to induce human alloantigen-specific anergy: a method to ameliorate graft-versus-host disease and extend the donor pool", <i>Blood</i> 97:4887-4893 (1996).		
	C39	GROUX, H., et al., "A CD4+ T-cell subset inhibits antigen-specific T-cell responses and prevents colitis," <i>Nature</i> , 389(6652):737-42 (1997 Oct 16).		
	C40	HAHN, B.H., <i>Dubois' Lupus Erythematosus</i> , 5th Ed. (1997), pp. 69-76 (D.J. Wallace et al. eds., Williams and Wilkins, Baltimore).		
	C41	HALVERSON et al., "In Vitro Generation of Allospecific Human CD8 <sup>+</sup> T Cells of Tc1 and Tc2 Phenotype," <i>Blood</i> , 90(5):2089-2096 (September 1997).		
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	C43	HEITGER et al., "Essential Role of the Thymus to Reconstitute Naïve (CD45RA <sup>+</sup> ) T-Helper Cells After Human Allogeneic Bone Marrow Transplantation", <i>Blood</i> , 90(2):850-857 (July 1997).		
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	C48	HORWITZ DA, et al., "Decreased production of interleukin-12 and other Th1-type cytokines in patients with recent-onset systemic lupus erythematosus." <i>Arthritis Rheum.</i> , 41(5):838-44 (1998 May).		
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	C52	JACKSON AL, et al., "Restricted expression of p55 interleukin 2 receptor (CD25) on normal T cells." <i>Clin Immunol Immunopathol.</i> , 54(1):126-33 (1990 Jan).		
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	C57	KLINMAN DM, et al., "Quantitation of IgM- and IgG-secreting B cells in the peripheral blood of patients with systemic lupus erythematosus." <i>Arthritis Rheum.</i> , 34(11):1404-10 (1991 Nov).		
	C58	KOH et al., "Adoptive cellular immunotherapy: NK cells and bone marrow transplantation," <i>Histol Histopathol</i> , 15:1201-1210 (2000).		
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	C61	KRENGER et al., "Polarized type 2 alloreactive CD4+ and CD8+ donor T cells fail to induce experimental acute graft-versus-host disease", <i>J Immunol</i> 153:585-593 (1995).		
	C62	LANCASTER, F., et al., "Anti-idiotypic T cells suppress rejection of renal allografts in rats," <i>Nature.</i> , 1985 May 23-29;315(6017):336-7.		
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	C64	LARSEN, C.P., et al., "Long-term acceptance of skin and cardiac allografts after blocking CD40 and CD28 pathways," <i>Nature</i> , 381(6581):434-8 (1996 May 30).		
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	C67	MARTIN et al., "Effects of in vitro depletion of T cells in HLA-identical allogeneic marrow grafts", <i>Blood</i> 66:664-672 (1985).		
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	C71	MASSAGUE J., "The transforming growth factor-beta family," <i>Annu Rev Cell Biol.</i> , 6:597-641 (1990).		
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	C73	MIZUOCHI, T., et al., "Both L3T4+ and Lyt-2+ helper T cells initiate cytotoxic T lymphocyte responses against allogeneic major histocompatibility antigens but not against trinitrophenyl-modified self," <i>J Exp Med.</i> , 62(2):427-43 (1985 Aug 1).		
	C74	MORRIS, "Prevention and treatment of allograft rejection in vivo by rapamycin: molecular and cellular mechanisms of action", <i>Ann NY Acad Sci</i> 685:68-72 (1993).		
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	C77	OHTSUKA, K., et al., "Decreased Production of TGF- $\beta$ by Lymphocytes from Patients with Systemic Lupus Erythematosus," <i>J. Immunol.</i> , 160:2539-2545 (1998).		
	C78	OSWALD, et al., "IL-10 Synergizes with IL-4 and Transforming Growth Factor-Beta to Inhibit macrophage Cytotoxic Activity," <i>J Immunology</i> 148(11):3578-3582 (1992).		
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	C80	PATTERSON et al., "Graft rejection following HLA matched T-lymphocyte depleted bone marrow transplantation", <i>Br J Haematol</i> 63:221-230 (1986).		
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	C83	PESCOVITZ, M.D., et al., "Effect of class II antigen matching on renal allograft survival in miniature swine," <i>J Exp Med.</i> , 160(5):1495-508 (1984 Nov 1).		
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	C91	RODT, H., "Anti-lymphocytic antibodies and marrow transplantation. 3. Effect of heterologous anti-brain antibodies on acute secondary disease in mice", <i>Eur. J. Immunol.</i> , 4:25-29 (1974).		
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	C104	STRAND, V., "Approaches to the management of systemic lupus erythematosus," <i>Current Opinion in Rheumatology</i> , 9:410-420 (1997).		
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	C111	TAKAHASHI T, et al., "Immunologic self-tolerance maintained by CD25+CD4+ naturally anergic and suppressive T cells: induction of autoimmune disease by breaking their anergic/suppressive state." Int Immunol., 10(12):1969-80 (1998 Dec).		
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	C117	VENDETTI, S., et al., "Anergic T cells inhibit the antigen-presenting function of dendritic cells," J Immunol., 165(3):1175-81(2000 Aug 1).		
	C118	VERBANAC, K.M., et al., "A role for transforming growth factor-beta in the veto mechanism in transplant tolerance," Transplantation, 57(6):893-900 (1994 Mar 27).		
	C119	VIA et al., "Critical Role of interleukin-2 in the development of acute graft-versus-host disease", International Immunol 5:565-572 (1993).		
	C120	WAHL SM. "Transforming growth factor beta: the good, the bad, and the ugly." J Exp Med., 180(5):1587-90 (1994 Nov 1).		
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